

biological precursor thereof is selected from the group consisting of pregnenolone, 17 α -hydroxypregnenolone, 5-androstenediol, DHEA sulfate, 17 α -hydroxypregnenolone sulfate and 5-androstenediol sulfate.

23. (Twice Amended) A method of pro-pigmenting superficial body growths, comprising applying DHEA or at least one biological precursor thereof or metabolic derivative thereof to superficial body growths, wherein said metabolic derivative thereof is selected from the group consisting of 5-androstene-3 β ,17 β -diol, 5-androstene-3 β ,17 β -diol sulfate and 4-androstene-3,17-dione and said biological precursor thereof is selected from the group consisting of pregnenolone, 17 α -hydroxypregnenolone, 5-androstenediol, DHEA sulfate, 17 α -hydroxypregnenolone sulfate and 5-androstenediol sulfate.--

SUPPORT FOR THE AMENDMENT

The amendment to Claims 12 and 23 is found at page 5, lines 15-17, of the specification and in Claims 14 and 25. No new matter is believed to be introduced by the above amendment.

REMARKS

Claims 12-13, 16-24, and 27-33 are pending. Favorable reconsideration is respectfully requested.

At the outset, Applicants thank Examiner Willis for withdrawing the finality of the Office Action of December 12, 2001. Further, Applicants thank Examiner Willis for indicating that the corrected drawings received on August 12, 2002, are acceptable.

The rejections of Claims 12-14 and 16-25, 27-30, and 22 under 35 U.S.C. § 102(b) and/or 103(a) over Grollier et al., Ribier, and/or Diaz et al. are obviated by the above amendment. None of Grollier et al., Ribier, or Diaz et al. disclose or suggest the claimed methods of use of DHEA, biological precursors of DHEA, or metabolic derivatives of DHEA.

One aspect of the claimed invention is a method of depigmenting and/or bleaching the skin and/or improving the homogeneity of the color of the skin by applying DHEA or at least one biological precursor thereof or metabolic derivative thereof to the skin (See amended Claim 12 above). The claimed biological precursor of DHEA is selected from the group consisting of pregnenolone, 17 α -hydroxypregnenolone, 5-androstanediol, DHEA sulfate, 17 α -hydroxypregnenolone sulfate and 5-androstanediol sulfate (See amended Claim 12 above). The claimed metabolic derivatives of DHEA may be selected from the group consisting of 5-androstene-3 β ,17 β -diol, 5-androstene-3 β ,17 β -diol sulfate and 4-androstene-3,17-dione (See amended Claim 12 above).

Grollier et al. discloses compositions for combating skin blemishes by depigmenting the skin (see column 1, lines 10-15). As noted by the Examiner, the composition disclosed by Grollier et al. contains **cholesterol**.

Ribier discloses compositions and methods of depigmenting (see column 1, lines 9-20). As noted by the Examiner, Ribier discloses compositions containing **cholesterol** (see column 4, lines 23-67).

Diaz et al. discloses a method of pigmentation of the hair or nails by administering a comparable composition (see column 2, lines 35-40). As noted by the Examiner, Diaz et al. discloses a composition containing **cholesterol**.

In contrast to Grollier et al., Ribier, and Diaz et al., the claimed biological precursor of DHEA is selected from the group consisting of pregnenolone, 17 α -hydroxypregnenolone, 5-androstanediol, DHEA sulfate, 17 α -hydroxypregnenolone sulfate and 5-androstanediol sulfate (See amended Claim 12 above). More specifically, the claimed biological precursor of DHEA is **not cholesterol**. Since Grollier et al., Ribier, and Diaz et al. fail to disclose applying a composition containing any of the claimed biological precursors, none of none of these references disclose or suggest the claimed invention. Accordingly, withdrawal of these grounds of rejection is respectfully requested.

The rejection of Claims 20-22 and 31-33 under 35 U.S.C. § 112, second paragraph, is traversed. The Office has taken the position that the recitation of the term "derivative" is indefinite in these dependent claims. Applicants respectfully traverse the rejection on the basis that chemical compounds may be claimed by a name that adequately describes the material. In this regard, Claims 20-22 and 31-33 clearly indicate the claimed chemical compound by name.

Further, adequate descriptions of these chemical compounds are provided by example in the present specification, in combination with their description, to clearly define the scope of such terms (see page 5, lines 18-20, page 7, line 28 to page 9, line 6). In addition, the present specification provides numerous citations to appropriate references at page 9, line 5-6, of the specification.¹ Applicants respectfully submit that since the chemical compounds are claimed by name, and since adequate description and direction is provided in the specification to define such compounds, one of ordinary skill in the art would understand the

¹These references are incorporated by reference therein.

meaning of the term "derivatives" as used in the independent claims.² Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of Claims 22 and 23 under 35 U.S.C. § 112, second paragraph, is traversed. The Office contends that the phrase "HMG-COA reductase inhibitor" is indefinite because this phrase allegedly does not define any compound with chemical and/or physical characteristics, but only by functional properties. The Office further maintains that a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed invention.

Applicants have clearly defined "HMG-COA reductase inhibitors" at page 10, lines 9-12, of the specification as including those described in patent application EP-738510.³ Moreover, Applicants have provided the Office with a copy of this reference, and the Office has indicated on July 17, 2001 that this disclosure has been fully considered. This specification description, in combination with the descriptive name of the claimed inhibitors provides sufficient, definite description in compliance with 35 U.S.C. § 112. Accordingly, withdrawal of this ground of rejection is respectfully requested.

²Applicants have provided the Office with the disclosures of these references which are incorporated by reference. The Office has indicated on July 17, 2001, that each of these disclosures have been fully considered.

³This reference is incorporated by reference therein.

Applicants respectfully submit that the present application is now in condition for allowance. Early notice to this effect is respectfully requested. Should anything further be required to place this application in condition for allowance, the Examiner is requested to contact the undersigned by telephone.

Respectfully submitted,

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HEREWITH

IN THE CLAIMS

--Claims 14 and 25 are cancelled.--

Please amend the claims as follows.

--12. (Twice Amended) A method of depigmenting and/or bleaching for the skin and/or to improving the homogeneity of the color of the skin, comprising applying DHEA or at least one biological precursor thereof or metabolic derivative thereof to the skin, wherein said metabolic derivative thereof is selected from the group consisting of 5-androstene- $3\beta,17\beta$ -diol, 5-androstene- $3\beta,17\beta$ -diol sulfate and 4-androstene-3,17-dione and said biological precursor thereof is selected from the group consisting of pregnenolone, 17α -hydroxypregnenolone, 5-androstanediol, DHEA sulfate, 17α -hydroxypregnenolone sulfate and 5-androstanediol sulfate.

23. (Twice Amended) A method of pro-pigmenting superficial body growths, comprising applying DHEA or at least one biological precursor thereof or metabolic derivative thereof to superficial body growths, wherein said metabolic derivative thereof is selected from the group consisting of 5-androstene- $3\beta,17\beta$ -diol, 5-androstene- $3\beta,17\beta$ -diol sulfate and 4-androstene-3,17-dione and said biological precursor thereof is selected from the

group consisting of pregnenolone, 17 α -hydroxypregnenolone, 5-androstenediol, DHEA sulfate, 17 α -hydroxypregnenolone sulfate and 5-androstenediol sulfate.--